



CornellResearch

Where IRB and OSP Meet: Funded Human Participant Research and NFAs

Myles Gideon, MLS
IRB Manager
Office of Research Integrity & Assurance





Outline

- ❖ Cornell's Human Research Protection Program
- ❖ Federal Regulations
- ❖ What requires IRB/HRPP Review?
- ❖ Types of Review
- ❖ Externally Funded Research Requirements
- ❖ Collaborative/Multi-Site Research (incl. Subawards)
- ❖ Non-Financial Agreements
- ❖ IRB Protocol Submission Process
- ❖ Resources & Contacts
- ❖ Questions



Cornell's Human Research Protection Program

- Human Research Protection Program (HRPP)
 - Designed to help protect the rights and welfare of study participants involved in Cornell research
 - Compliance with federal, state, and local regulations; Cornell policies and procedures
 - ORIA staff, the IRB, researchers, OSP, sponsors, institutional leadership



- Institutional Review Board for Human Participant Research (the IRB)
 - Committee of faculty, staff, community members; scientists, non-scientists, experts
 - Conducts ethical review of research with human participants, assessing risks

Note: Weill Cornell Medicine has its own IRBs



Relevant Federal Regulations

• 45 CFR 46 - Department of Health & Human Services

- Subpart A, aka "**The Common Rule**" (revised 2018)
- Subparts B-D: Additional Protections for Pregnant Women, Human Fetuses and Neonates; Prisoners; Children

Agencies that have signed onto the Common Rule:

- | | | |
|--------------------------------------|------------------------------------|--|
| • Agency for Int'l Development | • Dept. of Energy | • Dept. of Veteran Affairs |
| • Central Intelligence Agency | • Dept. of Health & Human Services | • Environmental Protection Agency |
| • Consumer Product Safety Commission | • Dept. of Homeland Security | • Nat'l Aeronautics & Space Admin. |
| • Dept. of Agriculture | • Dept. of Housing & Urban Dev. | • Nat'l Science Foundation |
| • Dept. of Commerce | • Dept. of Justice | • Office of the Director of Nat'l Intelligence |
| • Dept. of Defense | • Dept. of Labor | • Social Security Admin. |
| • Dept. of Education | • Dept. of Transportation | |





Federal Regulations, cont.

- 21 CFR 50 & 56 -- FDA regulations
- 45 CFR 160 & 164 -- HIPAA
- 34 CFR 97, 98, 99 -- DOEd (incl. FERPA)
- DOJ, EPA, DOE, DOD (Common Rule+)
- NIH [human subjects research policies](#)





What is covered by Cornell's HRPP?

Activities or projects that...

- involve human participants

AND

- are defined as research

AND

- Cornell is “engaged”





Definitions

- **Human participants:** "...living individuals about whom an investigator.... conducting research (1) obtains info/biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the info/biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Citation: [45 CFR 46.102](#)



Definitions, cont.

- **Research:** “...a systematic investigation.... designed to develop or contribute to generalizable knowledge.”

-A few exclusions are written into the regulations, such as scholarly and journalistic activities that focus on specific people, and some public health surveillance activities.

Unsure if your project is human participant research? Check out our [decision tree](#).

Citation: [45 CFR 46.102](#)



Definitions, further cont.

- **Engaged:**
 - Cornell is engaged if its students, staff, or faculty are involved in collecting data/biospecimens, obtain informed consent, or obtain identifiable private information.
 - Cornell is also considered engaged if it is the primary recipient of a grant/contract that is funding non-exempt human subjects research, even if those research activities will be carried out by investigators from other institutions.



If Cornell is engaged in human participant research, then our IRB must either approve (or exempt) the study or rely on another IRB for oversight.



Common Human Participant Research Activities

- Surveys, interviews, focus groups
- Observational research (e.g., shadowing individuals or observing classrooms)
- Collection or use of human biological samples
- Secondary use of identifiable, private data
- Testing new devices





Primary Types of Review

•Exemption from IRB Review

- Specific types of minimal risk research, dictated by the Common Rule
- Administrative (IRB staff) review required → exemption determination

•IRB Review

•Expedited

- Minimal risk research (but not eligible for exemption)
- One IRB member, reviewed on a rolling basis

•Convened Committee (aka Full Board)

- More than minimal risk, or unknown level of risk
- Reviewed at monthly IRB meeting





Special Types of Review

- Prescreening (Program Development) Review
 - To meet a funder's requirement for IRB approval if you haven't fully developed all research methods and materials
 - Provide basic details for a preliminary approval
 - A complete IRB review will still be needed at a future point in time
- Reliance (Authorization) Agreement
 - For multi-institution, non-exempt research projects
 - One IRB serves as the single IRB (sIRB) or 'IRB of Record' for the entire project
 - Agreement signed by the Institutional Official at each institution (facilitated by IRB staff)



Externally Funded Research Considerations

Human participant research must be reviewed and approved* by the Cornell IRB before funding is released and before research can begin.



** 'Approval' can mean IRB approval, exempt determination, prescreening approval, or finalization of a reliance agreement.*



Externally Funded Research, cont.

- **Proposal stage:** in the Compliances panel of RASS-SR, check the box for human participant research. If able, link to your Cornell IRB protocol. If you're not sure, contact the IRB office!
- **Award stage** (or JIT): must have IRB approval or exemption. Must link to a Cornell IRB protocol within RASS-SR (Compliances panel). **OSP staff will not finalize an award if there is a missing or pending IRB protocol** (or questions about human participant research compliance).



Externally Funded Research, further cont.

- Other federal regulatory requirements and considerations:
 - Clinical Trial requirements (i.e., specific FOAs, additional GCP training, posting on ClinicalTrials.gov)
 - Collaborative/multi-site studies: Single IRB likely required for non-exempt, federally funded research. Otherwise, all engaged institutions must obtain their own IRB review and approval.
 - NIH data management and sharing plans (effective 1/25/23)



Collaborative/Multi-Site Research

- NIH, other federal agencies: “Single IRB” (sIRB) requirement for non-exempt studies (one IRB of Record responsible for all sites). If non-funded, may still make sense to identify one sIRB.
- Multiple factors for determining the sIRB (complexity, procedures, involvement, location, etc.)
- Might need to use a commercial IRB (e.g., BRANY) if none of the engaged institutions is able/willing to serve as sIRB; consider as part of your budget.
- If an sIRB is needed, a Reliance/ Authorization Agreement will be needed. This can be requested through RASS-IRB.
- Contact the IRB office early in the process (especially if your funder requires that you identify the sIRB in the proposal)





Collaborative/Multi-Site Research, cont.

● Subawards

- If the subawardee is conducting human participant research, their institution will need to show proof of IRB approval, and if non-exempt, the Cornell PI likely will need to have an approved Cornell IRB protocol, as well (we are engaged, as the prime).
- For federally funded research, likely will need a single IRB (sIRB). Reliance agreement must be signed before the subaward will be released.
- OSP will always contact IRB staff to confirm compliance, and will not finalize the subaward until the IRB approvals are provided



Non-Financial Agreements

- Non-financial agreements (NFAs) are non-monetary arrangements that relate to the conduct of research.
 - Examples: Data Use Agreements (DUAs), Material Transfer Agreements (MTAs), Non-Disclosure Agreements (NDAs)
- Office of Sponsored Programs is responsible for reviewing and approving these agreements.
- IRB relevance: NFAs might be needed for certain human participant research projects
 - Secondary analysis of a restricted data set about humans (DUA)
 - Secondary analysis of human biological samples coming from another institution (MTA)





Non-Financial Agreements, cont.

- Process note: OSP's review and approval of an NFA is separate from the IRB review of the related project.
 - The IRB might ask for a copy of the NFA, if it informs their review
 - OSP will check to make sure an NFA that involves human participant research* is linked to an approved IRB protocol in RASS and will check with IRB staff if that is missing (or unclear).

**Receipt of de-identified samples or data may not always constitute human participant research, depending on the relationship between the Cornell researcher and those who collected the data/samples. When in doubt, contact the IRB office.*



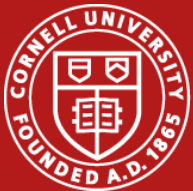
Non-Financial Agreements, further cont.

- HIPAA Note: The Cornell-Ithaca campuses (Ithaca, Geneva, Tech) are not covered under HIPAA for research purposes, so protected health information (PHI) cannot be stored on Cornell servers (and OSP will not approve an NFA that describes PHI being sent to Cornell). Contact the IRB office to discuss options.



IRB Protocol Submission Process

- Joined the RASS platform (“RASS-IRB”) in February 2022
- Everything in one place (initial protocol submissions, review communication, approvals; amendments; continuing reviews; protocol deviation reporting; adverse event reporting)
- Connections between IRB protocols and proposals/awards, non-financial agreements, and conflict of interest (COI) reports
- Time frames (at minimum): 2-3 days for Prescreenings; 1-2 weeks for amendments; 2-3 weeks for Exempt initial reviews, 3-4 weeks Expedited initial reviews, 4-6 weeks for all Full Board reviews. Certain times of year are busier (e.g., mid-semester).



Resources & Contacts

- Contact the IRB office: irbhp@cornell.edu
 - Myles Gideon, IRB Manager, mbg223, 607-255-6182
 - Lydia Galarneau, IRB Compliance Assistant
 - Vanessa McCaffery, IRB Administrator
 - Joyel Moeller, IRB Administrator
 - Valerie Ziarniak, IRB Administrator
- Schedule IRB staff consultations via [Bookings](#)
- IRB Website: <https://researchservices.cornell.edu/compliance/human-research>
- RASS-IRB System: <https://rass.cornell.edu/irb>
 - Guide to Using RASS Site (how-to documentation, videos of training sessions):
<http://guide.rass.cornell.edu>





Questions?

Ethics
IRB
Human
Subjects
Monitoring
Compliance
Justice
Beneficence
Respect
Education
Research